

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. The ingredient also may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 13559, Apr. 5, 1985]

§ 184.1434 Magnesium phosphate.

(a) Magnesium phosphate includes both magnesium phosphate, dibasic, and magnesium phosphate, tribasic. Magnesium phosphate, dibasic ($\text{MgHPO}_4 \cdot 3\text{H}_2\text{O}$, CAS Reg. No. 7782-0975-094) occurs naturally as the white, crystalline mineral newberyite. It is prepared commercially as a precipitate formed by treating a solution of magnesium sulfate with disodium phosphate under controlled conditions. Magnesium phosphate, tribasic ($\text{Mg}_3(\text{PO}_4)_2 \cdot x\text{H}_2\text{O}$, CAS Reg. No. 7727-0987-091) may contain 4, 5, or 8 molecules of water of hydration. It is produced as a precipitate from a solution of magnesite with phosphoric acid.

(b) Magnesium phosphate, dibasic, meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 179, which is incorporated by reference. Magnesium phosphate, tribasic, meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 180, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter and a pH

control agent as defined in § 170.3(o)(23) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. The ingredient also may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 13560, Apr. 5, 1985]

§ 184.1440 Magnesium stearate.

(a) Magnesium stearate ($\text{Mg}(\text{C}_{17}\text{H}_{35}\text{COO})_2$, CAS Reg. No. 557-04-0) is the magnesium salt of stearic acid. It is produced as a white precipitate by the addition of an aqueous solution of magnesium chloride to an aqueous solution of sodium stearate derived from stearic acid that is obtained from edible sources and that conforms to the requirements of § 172.860(b)(2) of this chapter.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 182, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a lubricant and release agent as defined in § 170.3(o)(18) of this chapter; a nutrient supplement as defined in § 170.3(o)(20) of this chapter; and a processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in

this section do not exist or have been waived.

[50 FR 13560, Apr. 5, 1985]

§ 184.1443 Magnesium sulfate.

(a) Magnesium sulfate ($\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$, CAS Reg. No. 10034-99-8) occurs naturally as the mineral epsomite. It is prepared by neutralization of magnesium oxide, hydroxide, or carbonate with sulfuric acid and evaporating the solution to crystallization.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 183, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavor enhancer as defined in § 170.3(o)(11) of this chapter; a nutrient supplement as defined in § 170.3(o)(20) of this chapter; and a processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 13560, Apr. 5, 1985]

§ 184.1443a Malt.

(a) Malt is an enzyme preparation obtained from barley which has been softened by a series of steeping operations and germinated under controlled conditions. It is a brown, sweet, and viscous liquid or a white to tan powder. Its characterizing enzyme activities are α -amylase (EC 3.2.1.1.) and β -amylase (EC 3.2.1.2).

(b) The ingredient meets the general requirements and additional require-

ments for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or may be examined at the Office of Premarket Approval (HFS-200), Food and Drug Administration, 200 C St., SW., Washington, DC, and the Office of the Federal Register, 800 North Capitol St., NW., suite 700, Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in § 170.3(o)(9) of this chapter to hydrolyze starch or starch-derived polysaccharides.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

[60 FR 32911, June 26, 1995]

§ 184.1444 Maltodextrin.

(a) Maltodextrin ($(\text{C}_6\text{H}_{10}\text{O}_5)_n$, CAS Reg. No. 9050-36-6) is a nonsweet nutritive saccharide polymer that consists of D-glucose units linked primarily by α -1-4 bonds and that has a dextrose equivalent (D.E.) of less than 20. It is prepared as a white powder or concentrated solution by partial hydrolysis of corn starch, potato starch, or rice starch with safe and suitable acids and enzymes.

(b)(1) Maltodextrin derived from corn starch must be of a purity suitable for its intended use.

(2) Maltodextrin derived from potato starch meets the specifications of the Food Chemicals Codex, 3d ed., 3d supp. (1992), p. 125, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC 20408, or at the Division of Petition Control (HFS-217),